

## SETTLEMENT AGREEMENT

### I. Recitals

1. Parties. The Parties to this Settlement Agreement ("Agreement") are the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS"), and Clarence M. (Larry) Oneto, Cindy Oneto, and American Medical Imaging, Inc. ("AMI")(Clarence Oneto, Cindy Oneto, and AMI are collectively known as "Respondents").

2. Description of the Anti-Kickback Statute. 42 U.S.C. § 1320a-7b(b)(2) provides for criminal sanctions against:

whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.

3. Description of the Stark Statute. 42 U.S.C. § 1395nn provides that:

(a)(1) [I]f a physician (or immediate family member of such physician) has a financial relationship with an entity specified in paragraph (2), then—

(A) the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this subchapter, and

(B) the entity may not present or cause to be presented a claim under [Medicare] or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to a referral prohibited under subparagraph (A).

(2) [A] financial relationship of a physician (or an immediate family of such physician) with an entity specified in this paragraph is—

(B). . . a compensation arrangement (as defined in subsection (h)(1) of this section) between the physician (or an immediate family member of such physician) and the entity.

Ultrasound services are designated health services under 42 U.S.C. § 1395nn(h)(6)(D).

4. Description of the Civil Monetary Penalty for Kickbacks. 42 U.S.C. § 1320a-7a(a)(7), a provision of the Civil Monetary Penalties Law (“CMPL”), provides that any person that commits an act described in 42 U.S.C. §§ 1320a-7b(b)(1) or (b)(2) shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty of not more than \$50,000 for each such act. In addition, such a person shall be subject to an assessment of damages of not more than three times the total amount of remuneration offered, paid, solicited, or received, without regard to whether a portion of such remuneration was offered, paid, solicited, or received for a lawful purpose. In addition, the CMPL authorizes HHS to exclude a person subject to such penalties from participation in the Federal health care programs.

5. Description of the Civil Monetary Penalty for Violations of the Stark Statute. 42 U.S.C. § 1395nn(g)(3) provides that any person that presents or causes to be presented a bill or a claim for a service that such person knows or should know is for a service for which payment may not be made based upon 42 U.S.C. § 1395nn, shall be subject to a civil money penalty of not more than \$15,000 for each such service. In addition, such a person shall be subject to an assessment of not more than three times the amount claimed for such services. In addition, HHS may exclude a person subject to such penalties from participation in the Federal health care programs.

6. Description of Permissive Exclusion Authority for Kickbacks. 42 U.S.C. § 1320a-7(b)(7) authorizes HHS to exclude from participation in any Federal health care program any person who has committed an act which is described in 42 U.S.C. §§ 1320a-7a, 1320a-7b, or 1320a-8.

7. Description of the Civil Money Penalty for False Claims. 42 U.S.C. § 1320a-7a(1)(A) and (B), a provision of the Civil Monetary Penalties Law (“CMPL”), provides that:

(a) Any person (including an organization, agency, or other entity, but excluding a beneficiary, as defined in subsection (i)(5)) that—

(1) knowingly presents or causes to be presented to an officer, employee, or agent of the United States, or of any State agency . . . , a claim . . . that the Secretary determines—

(A) is for a medical or other item or service that the person knows or should know was not provided as claimed, including any person who engages in a pattern or practice of presenting or causing to be presented a claim for an item or service that is based on a code that the person knows or should know will result in a greater payment to the person than the code the person knows or should know is applicable to the item or service actually provided,

(B) is for a medical or other item or service and the person knows or should know the claim is false or fraudulent,

shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty of not more than \$10,000 for each item or service . . . In addition, [HHS] may make a determination in the same proceeding to exclude the person from participation in the Federal health care programs.

8. Notices of Proposed Determination. On February 6, 2002, the OIG issued a Notice of Proposed Determination (“Notice”) to AMI pursuant to the CMPL and 42 U.S.C. § 1395nn(g)(3), notifying AMI that the OIG was proposing penalties, assessments, and exclusion against AMI. The grounds upon which the OIG sought such relief are set forth fully and completely in the Notice. In its Notice, the OIG contends that AMI paid referral fees to seven obstetric and gynecological physicians in Cookeville, Tennessee, during the period from August 1997 through April 2000 to induce the referral of Medicare beneficiaries to AMI for ultrasound studies and diagnostic testing. The OIG contends that these referral fees paid by Respondents constituted illegal remuneration under 42 U.S.C. § 1320a-7b(b)(2), and an improper financial relationship under 42 U.S.C. § 1395nn, and that the OIG could impose civil monetary penalties, and assessments against Respondents under 42 U.S.C. §§ 1320a-7a(a)(7) and 1395nn(g)(3) and seek to exclude AMI under 42 U.S.C. § 1320a-7(b)(7).

Additionally, on February 6, 2002, the OIG issued a second Notice to AMI and Cindy Oneto pursuant to the CMPL, notifying them that the OIG was proposing penalties, assessments and exclusion against Cindy Oneto and AMI for separate conduct unrelated to the conduct identified in the prior paragraph. The grounds upon which the OIG sought such relief are set forth more fully and completely in that Notice. In its Notice, the OIG

contends that during the period August 1997 through November 2000, AMI and Cindy Oneto submitted or caused to be submitted to Medicare claims for medical items or services that they knew or should have known were: (A) not provided as claimed; or (B) false or fraudulent. As specifically set forth in the Notice, the OIG alleges the improper claims were for: (i) vascular ultrasound and bone density testing performed by technicians who lacked the training and certification required by state licensing boards or national credentialing bodies to perform such tests; (ii) procedures for which there was no physician order as required; (iii) medically unnecessary tests; and (iv) services previously claimed and rejected by Medicare, resubmitted using different ICD-9 diagnosis codes, that were not clinically indicated in the patients' medical records, and that were selected based on ICD-9 codes historically reimbursable under Medicare. The OIG contends that it could impose civil monetary penalties, and assessments against Respondents under 42 U.S.C. §§ 1320a-7a(a)(1)(A) or (B), and seek to exclude Respondents under 42 U.S.C. § 1320a-7(b)(7).

9. No Admission of Liability. Respondents deny the OIG's allegations and any resulting liability for the conduct described in the Notices of Proposed Determination.

10. Intention of Parties to Effect Settlement. In order to avoid the uncertainty and expense of litigation, the Parties agree to resolve this matter according to the terms of this Agreement.

## II. Terms and Conditions

11. Payments. Respondents agree to pay to the OIG \$225,000. All payments shall be made in the form of a certified or cashier's check, made payable to the Secretary, United States Department of Health and Human Services. Full payment is due upon signing of the Settlement Agreement by Respondents.

12. Corporate Dissolution and Winding up of Affairs of AMI. Respondents agree that AMI will cease to do business on or before June 14, 2002. AMI will file with the state of Tennessee Articles of Dissolution on or before June 14, 2002. AMI further agrees that it will diligently pursue the winding up of the corporation's affairs. During the interim period between when the Settlement Agreement is executed and AMI files its certificate of dissolution with the state of Tennessee, AMI agrees that it will retain an outside firm to prepare and submit all its claims for reimbursement to Federal health care programs. AMI is required to provide the OIG written notification of its retention of an outside firm to prepare and submit its claims for reimbursement. Additionally AMI is required to provide the OIG a certified copy of its Articles of Dissolution filed with the state of Tennessee; a copy of its tax clearance certificate obtained from the State

Department of Revenue, and a certified copy of its Articles of Termination. Such written notification and copies of corporate filings must be sent to: Sabrina Skeldon, Senior Counsel, Office of Counsel to the Inspector General, Department of Health and Human Services, 330 Independence Ave., S.W., Room 5527, Cohen Building, Washington, D.C. 20201.

13. Exclusion of AMI. In the event that AMI fails to file its Articles of Dissolution with the state of Tennessee prior to June 15, 2002, AMI agrees to be permanently excluded under 42 U.S.C. § 1320a-7a(a) from Medicare, Medicaid, and all other Federal health care programs as defined in 42 U.S.C. § 1320a-7b(f), and agrees to waive all rights to file a notice of appeal from the exclusion, either administratively or in any state or Federal court; and waives any further notice of this exclusion.

14. Exclusion of Clarence M. (Larry) Oneto From Federal Health Care Programs. In compromise and settlement of the claims of the OIG set forth in this Agreement, Clarence M. (Larry) Oneto agrees to be permanently excluded under 42 U.S.C. § 1320a-7(b)(7) from Medicare, Medicaid, and all other Federal health care programs as defined in 42 U.S.C. § 1320a-7b(f). Such exclusion will have national effect and will also apply to all other Federal procurement and non-procurement programs. Federal health care programs will not reimburse Clarence M. (Larry) Oneto or anyone else for goods or services, including administrative and management services, furnished, or ordered by Clarence M. (Larry) Oneto in any capacity. Clarence M. (Larry) Oneto waives any further notice of the exclusion, and agrees not to contest such exclusion either administratively or in any State or Federal court. Clarence M. (Larry) Oneto shall not personally, or through any entity he controls, e.g., through a direct or indirect ownership interest of five percent (5%) or more or as an officer, agent, or managing employee (as defined by 42 U.S.C. § 1320a-5(b)), submit or cause to be submitted claims for payment under any Federal health care program. Violation of the conditions of the exclusion may result in criminal prosecution, the imposition of civil monetary penalties and assessments, and an additional period of exclusion. Clarence M. (Larry) Oneto further agrees to hold the Federal health care programs, and all Federal beneficiaries and/or sponsors, harmless from any financial responsibility for goods or services furnished, ordered, or prescribed to such beneficiaries or sponsors after the effective date of the exclusion. This exclusion will be effective upon the date that AMI files its Articles of Dissolution with the state of Tennessee, or June 15, 2002, whichever is earlier.

15. Certification by Cindy Oneto. In compromise and settlement of the claims of the OIG, Cindy Oneto agrees to submit to the OIG certifications for a five year period following the execution of this Settlement Agreement. The certifications are required annually, or more frequently in the event there is a material change in her place of

employment or residence. The first certification shall be received by the OIG no later than 30 days after the execution of the Settlement Agreement. Subsequent certifications by Cindy Oneto shall be received by the OIG no later than the one year anniversaries from the due date of the first certification report, and within 30 days of any material change in the employment or location of residence of Cindy Oneto.

Each certification shall include:

1. A statement identifying Cindy Oneto's current residence, and place of employment.
2. A statement identifying the nature of her employment, and how her compensation is calculated, including whether her compensation is a flat salary or is calculated on a commission, or a percentage based on the value of the services generated by her or any agent acting on her behalf, that are reimbursable by Federal health care programs (i.e., a percentage or volume-based compensation arrangement).
3. A statement of whether Cindy Oneto has received any financial incentives to induce the ordering or providing of services reimbursable under Federal health care programs; and if she has, a description of the source that offered and paid the incentives, the amounts, the form the incentives took, and other relevant facts associated with such incentives.
4. A statement of whether Cindy Oneto has offered, paid, solicited, or received any remuneration to or from any health care provider who may be in a position to refer Federal health care program patients or business to Cindy Oneto or any employer of Cindy Oneto (or receive referrals from Cindy Oneto, or any agents acting on her behalf). The statement should identify whether the offer, payment, solicitation, or receipt was made under a written arrangement that was reviewed by an attorney with expertise in legal requirements relevant to such transactions, e.g., 42 U.S.C. §§ 1320a-7b(b) and 1395nn. If any such remuneration has been offered, paid, solicited, or received, a statement should be included describing all the sources/recipients of such remuneration, the amounts, the forms the remuneration took, and other relevant facts associated with such remuneration.
5. A statement of whether Cindy Oneto has submitted claims for reimbursement to any Federal health care program for services rendered by

her or any of her agents; whether she has overseen the submission of claims for reimbursement from any health care programs for services rendered by any entity she may be employed by, or for services rendered for her own benefit.

6. A statement of whether Cindy Oneto has either an active or a passive ownership interest in an entity, or acts in a management capacity for any entity that submits claims for reimbursement from Federal health care programs.

16. Notifications. Unless otherwise stated subsequent to the execution of this Agreement, all notifications, certifications and reports required under the terms of this Agreement shall be submitted to the following:

If to the OIG/HHS: Civil Recoveries Branch - Compliance Unit  
Office of Counsel to the Inspector General  
Office of Inspector General  
U.S. Department of Health and Human Services  
330 Independence Avenue, SW  
Cohen Building, Room 5527  
Washington, DC 20201  
Ph. 202.619.2078  
Fax 202.205.0604

If to Respondents: William T. Ramsey  
Neal & Harwell, PLC  
150 Fourth Avenue, North  
Suite 2000  
Nashville, TN 37219-2498  
Ph. 615.244.1713  
Fax 615.726.0573

Unless otherwise specified, all notifications, certifications and reports required by this Agreement may be made by certified mail, overnight mail, hand delivery or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

17. Breach and Default Provisions. Full and timely compliance by Cindy Oneto shall be expected throughout the duration of this Agreement with respect to the

obligations agreed to in paragraph 15. As a contractual remedy, Cindy Oneto and the OIG agree that failure to timely file the certifications required by paragraph 15, or the making of a material misrepresentation as to the information to which Cindy Oneto is required to certify shall lead to the following (in addition to any other legal actions the government may initiate): (1) the release granted to Cindy Oneto under paragraph 18 shall be rescinded; (2) the OIG may re-institute proceedings to exclude Cindy Oneto pursuant to 42 U.S.C. §§ 1320a-7(b)(7), 1320a-7a(a) or 1395nn(g)(3); and (3) Cindy Oneto may contest such action, except that she will not argue that such action is time-barred.

18. Tolling Agreement. Cindy Oneto agrees that the time between February 6, 2002, and the date in the future when the conditions described in paragraph 17 have occurred, and the OIG re-files an action seeking exclusion of Cindy Oneto (the "Tolling Time Period") will not be included in computing the time limit by any statute of limitations that may be applicable to the commencement of an action or administrative exclusion proceeding by the OIG against Cindy Oneto. Cindy Oneto agrees that any applicable statute of limitations shall be tolled with respect to the OIG during the Tolling Time Period and agrees not to at any time assert, plead or raise against the OIG in any fashion, whether by answer, motion, or otherwise, any defense or avoidance based on the running of any statute of limitations during any portion of the Tolling Time Period. Cindy Oneto agrees that the Tolling Time Period, or any portion thereof, shall not be used to raise any other defenses, including, but not limited to, laches, concerning the OIG's timeliness in commencing an administrative proceeding.

19. Release by the OIG. In consideration of the obligations of Respondents under this Agreement and conditioned upon the payment described in Paragraph 11 of this Agreement, the OIG releases Respondents from the claims (civil monetary penalties, assessments and exclusion) set forth in the Notices that it has against Respondents under 42 U.S.C. §§ 1320a-7b(b)(2), 1395nn, and 42 U.S.C. §§ 1320a-7a(a)(1)(A) or (B), subject to the terms of this Agreement. The OIG and Respondents further agree that the Notices will be dismissed with prejudice, subject to the terms of this Agreement. Neither the OIG nor HHS agree to waive any rights, obligations or causes of action other than those specifically referred to in this paragraph. This release is applicable only to the Respondents, and Respondents' successors, heirs, and assigns, and is not applicable in any manner to any other person, partnership, corporation, or other entity.

20. Release by Respondents. Respondents agree not to contest the amount due under this Agreement, and not to contest any remedy agreed to under this Agreement. Respondents waive all procedural rights granted under the CMPL (42 U.S.C. § 1320a-7a) and related regulations (42 C.F.R. Part 1003), and HHS claims collection regulations (45



C.F.R. Part 30), including, but not limited to, notice, hearing, and appeal with respect to the amount due.

21. Reservation of Claims. Notwithstanding any term of this Agreement, the OIG specifically reserves and excludes from the scope and terms of this Agreement as to any entity or person, including Respondents, their current or former employees or agents, successors or assigns, any of the following claims:

1. Any criminal, civil, or administrative claims arising under Title 26 U.S. Code (Internal Revenue Code);
2. Any mandatory exclusion under 42 U.S.C. § 1320a-7(a).
3. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct.

22. Binding on Successors. This Agreement is binding on the successors, heirs, and transferees of the Respondents.

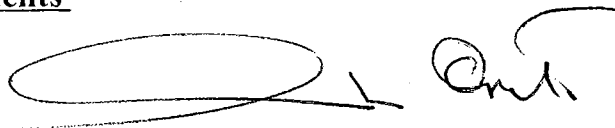
23. Costs. Each party to the Agreement shall bear its own costs.

24. Effect of Agreement. This Agreement contains a complete description of the bargain between the parties. All material representations, understandings, and promises of the Parties are contained in this Agreement. Any modifications must be set forth in writing and signed by all Parties. Respondents represent that this Agreement is entered into with knowledge of the events described herein, and having received the advice of legal counsel. Respondents further represent that this Agreement is voluntarily entered into in order to avoid litigation, without any degree of duress or compulsion.

25. Execution of Agreement. This Agreement shall become final and binding only upon signing by the Parties, and upon receipt by the OIG of complete and full payment as required in Paragraph 11.

Respondents

3-11-02  
Date

  
Clarence M. Oneto

Date

Cindy Oneto

Date

American Medical Imaging, Inc.

Its:

Date \_\_\_\_\_

D. McCarty Thornton

Chief Counsel to the Inspector General

Office of Inspector General

U.S. Department of Health & Human Services

Room 5527, Cohen Bldg.

330 Independence Ave., S.W.

Washington, D.C. 20201